K082828

OCT 1 4 2008

510(k) Summary of Safety and Effectiveness
SuturTek 360° Sternal Closure Device™

1. Sponsor/Manufacturer Name:

SuturTek Incorporated
51 Middlesex Street
North Chelmsford, Massachusetts 01863
Telephone: 978-251-8088
Fax: 978-251-8585

Contact:

Mr. Arthur Rankis
A. A. Rankis & Associates, Inc.
6 Brookside Circle
Acton, MA 01720
508 847 5961
arankis@aarankis.com

2. Device Name

Proprietary Name:	SuturTek 360° Sternal Closure Device™
Common/Usual Name:	(Classification Name) Suture, Nonabsorbable, Steel, Monofilament And Multifilament
Panel:	General Surgery
Product Code:	GAQ
878.4495	Suture, Nonabsorbable, Steel, Monofilament and Multifilament

3. Identification of Predicate or Legally Marketed Device

SuturTek FASTCLOSE™ Sternum Closure Device™ K032468

4. Device Description and Operation

The SuturTek 360° Sternal Closure Device™ is a an instrument that is used to pass stainless steel needles through sternum for fixation with stainless steel sutures. It is used to hold and close the sternum after a sternotomy.:

The device is sterilized before each use. The cartridge containing the needle (with suture attached) is loaded onto the distal end of the device. The needle is engaged by the device's internal drive mechanism and driven through the sternum to be sutured. The suture is thus passed completely through the tissue. Once the suture is in place, the device is withdrawn from the incision leaving the suture strand looped through the sternum. Additional interrupted stitches are placed in the same manner and then the ends of the suture are tied together in the usual fashion.

5. Intended Use

The SuturTek 360° Sternal Closure Device™ is intended for use during thoracic surgery to hold and close the sternum after a sternotomy.

It is designed to aid in the prevention of suture needlestick injuries.

6. Substantial Equivalence

Documentation was provided which demonstrated that the SuturTek 360° Sternal Closure Device™ is substantially equivalent to the predicate device, the SuturTek FASTCLOSE™ Sternum Closure Device™ K032468

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 14 2008

SuturTek Inc.
% A. A. Rankis & Associates, Inc.
Mr. Arthur Rankis
President
6 Brookside Circle
Acton, Massachusetts 01720

Re: K082828
Trade/Device Name: SuturTek 360° Sternal Closure Device™
Regulation Number: 21 CFR 878.4495
Regulation Name: Stainless steel suture
Regulatory Class: II
Product Code: GAQ
Dated: September 23, 2008
Received: September 25, 2008

Dear Mr. Rankis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082828

Device Name: Suturtek 360° Sternal Closure Device

Indications For Use:

The Suturtek 360° Sternal Closure Device is intended for use during thoracic surgery to hold and close the sternum after a sternotomy. It is designed to aid in the prevention of suture needle stick injuries.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082828